

69



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/509,677 | 03/30/2000 | NORITAKA II | Q58580 | 3130 |

7590 09/09/2005

SUGHRUE MION ZINN
MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

| |
|----------|
| EXAMINER |
|----------|

HUI, SAN MING R

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1617

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,677

Applicant(s)

II ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,31-39,41,42,44-52 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,31-39,41,42,44-52 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

8-50-

DETAILED ACTION

Applicant's amendments filed June 2, 2005 have been entered. Claims 1-18, 20-30, 40, 43, and 53 have been cancelled. Claims 19, 31-39, 41-42, 44-52, and 54 are pending.

The outstanding rejections under 35 USC 112 with regard to claims 40 and 50 are withdrawn in view of the amendments filed June 2, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 54 recited the specific dosage forms such as solution, syrups, and tablets. However, no water, solvents, or any other pharmaceutically acceptable carriers are recited in the broadest claims 19 and 42. Therefore, it is not clear how the composition recited in claim 19 be formulated into solution, syrup, or tablets.

Response to Arguments

Applicant's arguments filed June 2, 2005 averring one of ordinary skill in the art would have known what the scope of the claim be in the light of the instant specification have been considered, but are not found persuasive. The remarks presented in the

Art Unit: 1617

response filed June 2, 2005 does not seem to address the question and issues raised in the office action mailed December 2, 2004. If the composition is excluding water as claimed in claim 19, how can one of ordinary skill in the art formulate a solution, which is recited in claims 41 and 54?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19, 31-39, 41-42, 44-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of JP 8 27033 ('033) and Remington's Pharmaceutical Sciences, 18th, 1990, 1290-1292 (Remington) in view of Merck Index, 11th ed., monograph 2279, page 354.

'033 teaches a composition containing theophylline, a drug that is unpleasant taste, and erythritol. '033 also teaches that erythritol can be used in an amount of 1-

Art Unit: 1617

99% in weight. It also teaches erythritol as useful to provide a refreshing sweetness and also being useful as fillers, anti-moisture agents, and stabilizer for pharmaceutical agents. '033 also teaches the erythritol containing composition can be added other additives.

Remington teaches a method of taste-masking is blending bitter-taste drug with sweet and forming insoluble compounds of the drugs such as insoluble salts (see page 1291, col. 2). Remington also teaches that polyhydroxy compounds with molecular weight greater than 300, halogenated substances and aliphatic thio compounds may have bitter taste (See page 1291, col. 2, first paragraph).

The primary references do not expressly teach the incorporation of erythritol and a pH balancing agent, in the herein claimed weight ratio, to a composition containing a drug with unpleasant-taste.

Cimetidine is known to have aliphatic thio structure as evidence in Merck Index.

It would be obvious to one ordinary skill in the art at the time the invention was made to incorporate erythritol and a pH balancing agent to a composition containing a drug with unpleasant-taste such as cimetidine.

One of ordinary skill in the art would have been motivated to incorporate erythritol and a pH balancing agent to a composition containing a drug with unpleasant-taste such as cimetidine. Erythritol can provide sweet taste and a pH balancing agents can help form an insoluble form of the drugs and thereby masking the unpleasant taste of cimetidine. The optimization of the effect parameters (e.g., amounts of the active and excipients) is within the purview of the skilled artisan.

Response to Arguments

Applicant's arguments filed June 2, 2005 averring the cited prior arts' failure to teach the specific mechanism as to how the alcohol sugar mask the unpleasant taste of the herein claimed drugs have been fully considered but they are not persuasive. The prior arts clearly teaches that erythritol as useful as sweetener. Therefore, combining erythritol with a drug, which is known to be bitter or having unpleasant taste, would be obvious in view of the prior arts' teachings. In response to applicant's argument that the cited prior arts' failure to teach the specific mechanism as to how the alcohol sugar mask the unpleasant taste of the herein claimed drugs, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, possessing the teachings of the cited prior arts, one of

Art Unit: 1617

ordinary skill in the art would have been motivated to incorporate erythritol with the drug having unpleasant taste, absent evidence to the contrary.

Applicant's arguments filed June 2, 2005 averring Examiner applying "obvious-to-try" reasoning have been considered, but are not found persuasive. In the instant case, the sweetening properties of erythritol would be reasonably expected to mask the bitter taste of theophylline and cimetidine. Therefore, it is not merely "obvious-to-try". The motivation and reasonable expectation of success are clearly provided by the cited prior arts.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-

Art Unit: 1617

0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
Art Unit 1617